

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4-6, 11-16, 18-19 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Kelley (US 1,234,038).

Kelley discloses a clamp member (FIGS 1-4) having top (6) and bottom portions (5) with a recess (at 14) formed there between, the top and bottom portions including first and second ends, the second ends being connected to one another (at 9) such that the top and bottom portions are movable between an open position in which the top and bottom portions are spaced a distance apart from one another, and a closed position in which the clamp member is capable of engaging a spinal fixation element disposed within the recess, the top and bottom portions including inferior and superior surfaces, respectively, (internal clamp surfaces of 5, 6) that extend from the recess to the first end. The clamp member further includes a bore (at 24, 25) extending through the top and bottom portions for receiving a locking mechanism (33) for locking the top and bottom portions in the closed position, the bore in at least one of the top and bottom portions being internally threaded (col. 4, lines 90-105) for mating with

corresponding threads formed on at least a portion of the locking mechanism, wherein the inferior and superior surfaces are configured to taper away from one another toward the first end along an entire length thereof from the recess to the first end when the locking mechanism is disposed in the bore extending through the top and bottom portions.

The recess (at 14) is formed in at least one of the inferior surface of the top portion and the superior surface of the bottom portion. The recess is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member. The recess has a concave shape such that the recess defines a substantially cylindrical recess when the clamp member is in the closed position.

The top and bottom portions are biased to a closed position such that a force greater than the biasing force must be applied to move the top and bottom portions to the open position. The top and bottom portions are biased to an open position such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed position. (See col. 4, lines 99-101)

The locking mechanism (33) is disposable through the bore and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between. The locking mechanism comprises a fastening element having a head (33, FIG. 3, right) and a shaft (33, FIG. 3, left), and wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in

Art Unit: 3733

the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element.

The fastening element includes a flange (36) formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device.

The bore in the top portion of the clamp member is internally threaded for mating with corresponding threads formed on at least a portion of the shaft.

The fastening element includes a mating element formed on a distal-most end (socket containing handle 36) thereof for mating with a driver tool (36). The mating element comprises a socket.

The clamp member is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position.

Claims 1, 4-6, 11-16, 18 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Andersen et al. (US 2002/0000027).

Andersen et al. disclose a clamp member (FIG. 2) having top (14) and bottom (16) portions with a recess (36, 38) formed there between, the top and bottom portions including first (FIG. 2, left) and second ends (FIG. 2, right), the second ends being connected to one another such that the top and bottom portions are movable between an open position in which the top and bottom portions are spaced a distance apart from one another, and a closed position in which the clamp member is capable of engaging a spinal fixation element disposed within the recess, the top and bottom portions including inferior and

superior surfaces, respectively, (internal clamp surfaces) that extend from the recess to the first end. The clamp member further includes a bore (44,48) extending through the top and bottom portions for receiving a locking mechanism (40) for locking the top and bottom portions in the closed position, the bore in at least one of the top and bottom portions being internally threaded (48) for mating with corresponding threads formed on at least a portion of the locking mechanism, wherein the inferior and superior surfaces are configured to taper away from one another toward the first end along an entire length thereof from the recess to the first end when the locking mechanism is disposed in the bore extending through the top and bottom portions.

The recess is formed in at least one of the inferior surface of the top portion and the superior surface of the bottom portion. The recess is formed in each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member. The recess has a concave shape such that the recess defines a substantially cylindrical recess when the clamp member is in the closed position.

The top and bottom portions are biased to a closed position such that a force greater than the biasing force must be applied to move the top and bottom portions to the open position. The top and bottom portions are biased to an open position such that a force greater than the biasing force must be applied to move the top and bottom portions to the closed position.

The locking mechanism is disposable through the bore and effective to lock the top and bottom portions in the closed position to retain a spinal fixation

Art Unit: 3733

element there between. The locking mechanism comprises a fastening element having a head (50) and a shaft (42), and wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element.

The fastening element includes a flange (52) formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device.

The bore in the top portion of the clamp member is internally threaded for mating with corresponding threads formed on at least a portion of the shaft.

The fastening element includes a mating element formed on a distal-most end (52) thereof for mating with a driver tool.

The clamp member is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which

Art Unit: 3733

said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kelley (US 1,234,038).

Regarding claims 17 and 25, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads formed on at least a portion of the shaft of Kelley being left-handed threads, since it is a configuration a person ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 17 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Andersen et al. (US 2002/0000027).

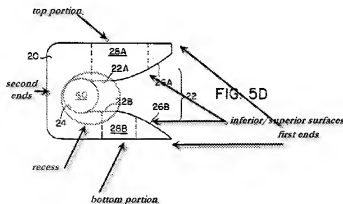
Regarding claims 17 and 25, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads formed on at least a portion of the shaft of Andersen et al. being left-handed threads, since it is a configuration a person ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Claims 1, 4-6, 11, 13-16, 18-19 and 22-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kraus (US 5,746,741) in view of Walulik (US 6,277,119).

Kraus discloses a clamp member (FIGS 5a-5d) having top and bottom portions with a recess (opening between top and bottom portions) formed there between, the top and bottom portions including first and second ends, the second

Art Unit: 3733

ends being connected to one another such that the top and bottom portions are movable between an open position in which the top and bottom portions are spaced a distance apart from one another, and a closed position in which the clamp member is capable of engaging a spinal fixation element disposed within the recess, the top and bottom portions including inferior and superior surfaces, respectively, that extend from the recess to the first end. The clamp member further includes a bore (28a, 28b) extending through the top and bottom portions for receiving a locking mechanism (40) for locking the top and bottom portions in the closed position, wherein the inferior and superior surfaces are configured to taper away from one another toward the first end along an entire length thereof from the recess to the first end when the locking mechanism is disposed in the bore extending through the top and bottom portions.



Closed Position

The recess is formed in at least one of the inferior surface of the top portion and the superior surface of the bottom portion. The recess is formed in

Art Unit: 3733

each of the inferior surface of the top portion and the superior surface of the bottom portion of the clamp member. The recess has a concave shape such that the recess defines a substantially cylindrical recess when the clamp member is in the closed position. The top and bottom portions are biased to a closed position such that a force greater than the biasing force must be applied to move the top and bottom portions to the open position. The locking mechanism (40) is disposable through the bore and effective to lock the top and bottom portions in the closed position to retain a spinal fixation element there between. The locking mechanism comprises a fastening element having a head and a shaft. The clamp member is formed from a material that allows the clamp member to deform around a spinal fixation element disposed between the top and bottom portions when the clamp member is locked in the closed position.

Kraus et al. disclose the claimed invention except for the claimed specifics of the locking means, *i.e.* the bore in at least one of the top and bottom portions being internally threaded for mating with corresponding threads formed on at least a portion of the locking mechanism, the locking mechanism comprising a fastening element, wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element, the fastening element including a flange formed there around and adapted to at least temporarily mate the fastening element to a spinal

anchoring device, the bore in the top portion of the clamp member being internally threaded for mating with corresponding threads formed on at least a portion of the shaft, and the fastening element including a mating element/socket formed on a distal-most end thereof for mating with a driver tool.

Walulik discloses a spinal connector including a locking means comprising a bore in at least one of the top and bottom portions being internally threaded for mating with corresponding threads formed on at least a portion of the locking mechanism, the locking mechanism comprising a fastening element, wherein one of the bore formed in the top portion and the bore formed in the bottom portion of the clamp member is adapted to freely rotatably receive the threaded shaft of the fastening element, and the other one of the bore formed in the top portion and the bore formed in the bottom portion is internally threaded to mate to threads formed on at least a portion of the shaft of the fastening element, the fastening element including a flange formed there around and adapted to at least temporarily mate the fastening element to a spinal anchoring device, the bore in the top portion of the clamp member being internally threaded for mating with corresponding threads formed on at least a portion of the shaft, and the fastening element including a mating element/socket formed on a distal-most end thereof for mating with a driver tool (see FIG. 5c) in order to provide a more secure connection between the two clamping jaws.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to construct the device of Kraus et al. with a locking means

in view of Walulik in order to provide a more secure connection between the two clamping jaws.

Furthermore, regarding claims 17 and 25, it would have been an obvious matter of design choice to one skilled in the art at the time the invention was made to construct the threads formed on at least a portion of the shaft of Kraus et al. in view of Walulik being left-handed threads, since it is a configuration a person ordinary skill in the art would find obvious for the purpose of providing threads. *In re Dailey and Eilers*, 149 USPQ 47 (1966).

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

Regarding Applicant's arguments in regards to the rejection over Kraus (US 5,746,741) in view of Walulik (US 6,277,119), the have been considered but are not deemed persuasive. Because the claimed recess can be considered to encompass a larger area that just the area of the circular recess, the recess of Kraus (see above marked-up figure) meets the claims.

The rejections are deemed proper.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

Art Unit: 3733

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARY HOFFMAN whose telephone number is (571)272-5566. The examiner can normally be reached on Monday-Thursday 10:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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